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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,189	LYNCH ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 23, 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-172* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-172* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 in part, drawn to a method of treating a neurological disorder associated synaptic vesicle function comprising administering a compound that modulates an SV2 protein, classified in class 514, subclass 2.

II. Claims 1-14 in part, drawn to a method of treating an endocrinological disorder comprising administering a compound that modulates an SV2 protein, classified in class 514, subclass 2.

III. Claims 15-35, drawn to a method of modulating the function of a SV2 protein in a cell, classified in for example class 435, subclass 7.21.

IV. Claims 36-49, 157-162 in part and 172, drawn to a method of discovering or modeling an interaction between an SV2 protein and a compound binding to the levetiracetam binding site using purely computational techniques, classified in for example class 435, subclass 7.21.

V. Claims 50-67, drawn to a method of identifying a leveiracetam binding site within an SV2 protein using mutagenesis, classified in for example class 435, subclass 7.21.

VI. Claims 68-92 and 138 in part, drawn to a method of assaying the interaction between SV2 protein and a second protein, classified in for example class 435, subclass 7.21.

VII. Claims 93-102, and 126-137, 139-156, drawn to a method of identifying a compound that modulates a neurological disorders associated with synaptic function, classified in for example class 435, subclass 7.21.

VIII. Claims 103-122, drawn to a method of identifying a cellular response to a compound of levetiracetam or its derivatives, classified in for example class 435, subclass 7.21.

IX. Claims 123, drawn to an isolated nucleic acid molecule, classified in for example class 536, subclass 235.

X. Claims 124-125, drawn to an isolated polypeptide, classified in for example class 530, subclass 350.

XI. Claims 138 in part, drawn to a method of identifying a binding partner for an SV2 protein, classified in for example class 435, subclass 7.21.

XII. Claim 157-162 in part, drawn to a method of discovering or modeling an interaction between an SV2 protein and a compound through the levetiracetam binding site using biochemical techniques, classified in for example class 435, subclass 7.21.

XIII Claim 157-162 in part, drawn to a method of discovering or modeling an interaction between an SV2 protein and a compound through the levetiracetam binding site using biophysical techniques, classified in for example class 435, subclass 7.21.

XIV. Claim 163, drawn to a method of discovering or modeling an interaction between an SV2 protein and a compound through the levetiracetam

binding site in an SV2 protein knockout or knockdown system, classified in for example class 345, subclass 7.21.

XV. Claim 164 and 168, drawn to a pharmaceutical composition other than levetiracetam derivatives, classified in for example class 435, subclass 7.21.

XVI. Claim 165 in part, 166, 169 in part and 170, drawn to a method of treating a neurological disorder comprising administering a compound other than levetiracetam derivatives, classified in for example class 514, subclass 2.

XVII. Claim 165 in part, 167, 169 in part and 171, drawn to a method of treating an endocrinological disorder comprising administering a compound other than levetiracetam derivatives, classified in for example class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions IX and X are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the polynucleotides in the group IX and polypeptides in the group X are patentably distinct inventions for the following reasons. First, polynucleotides and polypeptides are structurally distinct molecules. The former are the molecules consisting of purine and

pyrimidine, and the later are the molecules consisting of amino acids. A polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The different combination of purine and pyrmidine of group IX can generate a diverse range of sequences of polypeptides in the group X. For example, a point mutation of polynucleotides in the group IX can totally change the composition of polypeptides in the group X. Second, the biochemical properties of polypeptides are quite different from those of polynucleotides. The polypeptides can be isolated and analyzed using affinity chromatography or mass spectrophotometry. In addition, they are sensitive to proteinase, which is very different from polynucleotides that are sensitive to DNAase. Third, the biological function and use of polynucleotides are very different from those of polypeptides. Polynucleotides can be modified and used as a probe labeling with different fluorescence conjugates or radioisotopes to hybridize or detect the message of DNA/RNA. On the other hand, polypeptides function as biological agents that are more involved in targeting, recognition, trafficking, anchoring, and activity execution and regulation. The cellular distribution of polypeptides is very different from that of polynucleotides. Polypeptides could be located on the plasma membrane to function as a receptor to receive the signals. They could be also located in the cytosol or nucleus to regulate other proteins or DNA activity. In addition, each of the polypeptides or polynucleotides has a unique structural feature, which requires a unique search of the prior art. The Groups IX and X differ in structure and function as they are composed of divergent amino acids and have different biological functions. A reference

to one element would not constitute a reference to another. Thus, Inventions IX and X are patentably distinct.

4. Inventions XV and XVI-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the claimed pharmaceutical composition in the Group XV can be practiced with alternative compositions, such as DNA, antisense oligonucleotides, antibody or peptides. Thus, Inventions XV and XVI-XVII are patentably distinct.

5. Inventions I, II-V, VI-VIII, IX-X, XI-XIV, XV-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this instant case, the procedures, materials, equipments and outcomes are different among these inventions. For example, the materials and procedures used in the method of identifying a molecule modulating SV2 protein or interaction site of SV2 (Groups III-VIII, and XI-XIV) are very different from those in treatment of disease (Groups I, II, XVI and XVII). The technology and materials used in identifying compounds or molecules interacting with SV2 using computational techniques are not required for treatment of diseases associated with synaptic function. The procedures, materials and the equipments involved are very different between

these two categories of methods. In addition, the patient populations in Groups I and XVI are distinct from those in Groups II and XVII. The health and physiological conditions are very distinct. For example, the mental status, behavior, symptoms and the medication conditions as well as the etiology and pathology are very different. Furthermore, the materials in Groups IX and X are not required in Groups I-VIII and XI-XVII. Thus, the inventions I-XVII are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-XVII to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

10. This application contains claims directed to the following patentably distinct species of the claimed inventions I-XVII:

i. If Group I is elected, Applicant is required to elect a species of neurological disorder selected from A) epilepsy, B) Parkinson's disease, C) Parkinson's dyskinesias, D) migraine, E) Alzheimer's disease, F) neuropathic pain, G) essential tremor, H) cognitive disorders, or I) movement disorders. Currently, claim 1 is generic.

ii. If one of the Groups I-VIII is elected, Applicant is required to elected a species of derivative of Levetiracetam selected from A) N-alkylated 2-oxo-pyrrolidine derivatives, B) N-alkylated 2-oxo-piperidinyl derivatives, or C) N-alkylated 2-oxo-azepanyl derivatives. Currently, claims 1, 15, 36, 50, 68, 93, and 103 are generic.

iii. If Groups XVI is elected, Applicant is required to elect a species of neurological disorder selected from A) epilepsy, B) epileptogenesis, C) seizure disorders, D) convulsions, E) withdrawal seizures, F) bipolar disorders, G) mania; H) depression, I) anxiety, J) migraine, K) neuralgia, L) trigeminal neuralgia, M) chronic pain conditions, N) neuropathic pain, O) anaesthesia-related hyperexcitability, P) cerebral ischemia, Q) head trauma, R) myotonia, S) excitatory states provoked by drug or alcohol abuse, dependence or withdrawal,

T) stroke, U) myoclonus, V) essential tremor, W) tics, X) Tourette's syndrome, Y) dyskinesia, Z) spasticity, AA) movement disorders, BB) neonatal cerebral haemorrhage, CC) amyotrophic lateral sclerosis, DD) Parkinson's disease, EE) Alzheimer's disease, FF) a neurodegenerative disease, or GG) dementia. Currently, claims 165 and 169 are generic.

iv. If Group XVII is elected, Applicant is required to elect a species of endocrinological disorder selected from A) hypersecretion, B) giantism, C) dwarfism, D) adrenal-medulla-related diseases, E) hypoglycemia or F) circulation shock. Currently, claims 165 and 169 are generic.

v. If Group XII is elected, Applicant is required to elect a species of effect selected from A) biochemical, B) pharmaceutical, C) organismal, D) cellular or E) molecular. Currently, claim 157 is generic.

11. The species listed above are patentably distinct for the following reasons:

These species are distinct because they are different diseases and different compounds. The etiology and potential molecular mechanisms contributed to these pathological conditions are different. For example, the pathology and etiologies of Alzheimer's disease are very different from those of ischemia/stroke, neuropsychological disorders and endocrinological disorders. The patient populations in each pathological condition are also very distinct. The health status, the medication, the

diagnosis, and the physiological condition in patients with Alzheimer's disease are very different from those with ischemia/stroke, neuropsychological disorders and endocrinological disorders. It requires different diagnoses, equipments, steps and treatments for these different groups of patients. Therefore, each species of diseases is patentably distinct. In addition, each species of compound differs with respect to its composition, structural feature, function and use. The dose of use and effects in response to different compounds are also distinct. Thus, these species are patently distinct.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-XVII and a single species from groups i-v that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

18. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
December 12, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER